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ALERT

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on AIDS Legislation, Education, Research and Treatment.

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Ethical Issues Related to HIV-Infected Health Care Workers

(By Adele Stiles Resmer, Ph.D.)

Controversy continues in the U.S.A. surrounding public policy on the mandatory HIV testing of health care workers. The following Statement was presented by the AIDS National Interfaith Network to the U.S. Centers for Disease Control in public hearings on the issue. Rev. Adele Stiles Resmer, a medical ethicist, is ordained clergy and serves on the staff of the Evangelical Lutheran Church in America.

We in the religious community are often at the side of others during times of tragedy. We are well aware that none of us lives a life that is absolutely free of risk - that is not a realistic expectation. That is a difficult and sometimes frightening concept for people to grasp, but a very important one. Basing our policies and actions on a desire to mollify people's unrealistic hopes to live in a risk-free world is neither helpful nor responsible.

In the case of HIV-infected health care workers, (HCWs), based on existing evidence, it appears to us that the risks to patients are infinitely small, largely more theoretical than actual. On the other hand, the threat to the livelihoods of thousands of highly trained and dedicated people is quite real and possibly imminent. We do not believe that putting these people out of work is either just or justified. Especially in the midst of this epidemic which requires so much from our health care system, we cannot afford to hamper it further.

As people of faith concerned with the realm of ethics, our evaluation of the policy questions at hand are informed by two principles that lie at the heart of the provision of medical care. Nonmaleficence and beneficence, expressed in the Hippocratic Oath and the American Medical Association's Principles of Medical Ethics, have been essential to understanding the ethical parameters of medical care.

Nonmaleficence is the claim to do no harm. This includes not only actual harm, but also the risk of harm. Nonmaleficence also assumes that the HCW is thoughtful and behaves carefully. Nonmaleficence requires that HCWs not only avoid intentional harm to a patient but that they also acquire the knowledge and skill needed to provide appropriate care to patients.

The question must be, does care provided by HIV-infected HCWs, who are otherwise qualified, violate the standards of nonmaleficence? Current information about transmission and expectations of procedural precautions suggest rather clearly that those standards are not violated. Indeed, removing otherwise qualified HCWs from medical practice might well contribute to the harm of many patients by unnecessarily reducing the pool of qualified health care personnel. In certain geographic areas of the country, the removal of qualified personnel, simply because they are HIV-infected, could be catastrophic.

Beneficence is the claim that patients should benefit from a relationship with HCWs, particularly related to their health. This principle assumes that HCWs will not only avoid harm and benefit the patient, but that they will also evaluate the benefits of any particular action against the possible harm. This is particularly pertinent when patient care includes potential risk. Beneficence claims that if the risks of any particular procedure or care are reasonable in relationship to the expected benefits, then it is morally appropriate to carry out the procedure or participate in care.

This speaks clearly to discerning the appropriate response to HIV-infected HCWs. Assuming again that any given HCW is competent in the care they are providing, patients continue to benefit from the relationship and the care. There is no need to deprive a patient of medical care simply because their physician or dentist is HIV-infected given the low risk and the significantly greater benefit.

We believe that the claims of nonmaleficence and beneficence, which call for doing no harm to patients and providing benefits to them through the provisions of appropriate care, are essential to this discussion. Information to date suggests that there is extremely low risk of transmission of HIV from HCW to patient; we know that the benefits of good medical care are the difference between life and death for many. Neither of these important ethical principles which lie in the heart of medical practice are violated by the ongoing provision of all appropriate care by HIV-infected health care workers. In fact, violation of them may occur, not by the HCW, but by those who would prevent their ongoing participation in providing much needed medical care.

All of this suggests that protocols which stress the importance of universal precautions and infection control practices for health care personnel, including those who are HIV-infected, remain appropriate. All HCWs must meet the standards established for the provision of appropriate care. In light of current data and the ethical principles we've mentioned here, HIV-infected personnel should not be prohibited from providing any necessary care for their patients.

It is an important time to acknowledge people's fears and to redouble our efforts to educate. It is not the right time to accede to those fears and formulate policies which will protect no one and will actually increase human suffering. It is, in fact, immoral to do so. ▼

Zinc and B Vitamins in HIV: Overview and Interview

(By Denny Smith)

(reprinted with permission from Aids Treatment News, Issue 134, 9/6/91)

A number of medical journal reports in recent years have dealt with recurring questions of nutritional excesses and deficiencies in HIV infection. In particular, zinc, cobalamin (vitamin B12), and folic acid (folate) deficiencies, and excessive levels of copper have been connected to AIDS.

The May, 1991 edition of *AIDS Targeted Information Newsletter* (ATIN) included a good review of such studies, authored by Neil M.H. Graham, M.B.B.S., M.D., M.P.H., of the School of Hygiene and Public Health at The Johns Hopkins University. Dr. Graham raises the possibility of using abnormal fluctuations of micronutrients as markers for charting HIV progression. He also briefly addresses AIDS-associated weight loss or wasting syndrome, which, like the dificiencies mentioned above, may not necessarily be caused by malabsorption or diarrhea, and which may in turn increase susceptibility to new opportunistic infections.

We spoke to Dr. Graham by telephone and asked if he could elaborate on a few points in his review. Some of the studies to which he referred could create some confusion, since their results were often inconclusive or even contradictory.

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DS: If HIV infection is associated with decreased serum [blood] zinc levels, would you describe this as both a symptom and a blood marker?

NG: It is understandable that zinc deficiency could be looked at as a possible cofactor, because there is not doubt that a severe zinc deficiency can adversely affect immune functions. But it is difficult to say whether this is a cause, or an effect, of HIV progression. Inflammatory and neoplastic [cancer] processes are already known to decrease serum zinc, and increase serum copper. When we compared baseline zinc levels in seronegative and seropositive patients, we found that zinc intake had no relationship to disease progression in the seropositives. But levels of zinc in the blood did relate to progression, even after adjusting for CD4 [T-helper cell] count. This would imply that falling zinc levels represent a marker and not a contributor in HIV progression. So loading up with supplemental zinc may not help. In fact, one test-tube study suggested that HIV may actually require zinc in order to replicate.

DS: What would that mean in clinical care - would giving zinc to patients not be useful, or actually feed HIV?

NG: No one has done clinical trials to compare supplementation with no supplementation, so we can't say for certain one way or the other. In most people with HIV, zinc deficiency is not so serious that it would dramatically impair immune function, and thus warrant therapeutic supplementation. At this point we are simply likening it to a marker, such as neopterin or beta 2 microglobulin.

DS: How much of this is also true for vitamin B12 deficiency?

NG: That situation is a bit less equivocal. There are data showing that B12 injections may benefit some individuals with HIV-related neurological conditions, particularly neuropathies, dementia and demyelinating conditions. But none of the relevant studies have used very big numbers, or controlled trials. I think that trials of B12 supplementation are well worth pursuing.

DS: Several of our readers have told us that their neuropathy was improved by B12 injections. One person said that B6 also had this effect. I was interested in the connection you made in your review between neopterin and the metabolism of B vitamins.

NG: Yes. Two studies reported in *The Lancet* that folate metabolism seems to be altered by rising neopterin levels, particularly in children with HIV who have developed dementia.

DS: For years we have been hearing about possible connections between HIV progression and increased serum neopterin, but HIV clinicians haven't seemed to put much stock in it. Ostensibly this provides a fresh reason to look into neopterin as a marker or cofactor.

NG: I think that's right. It certainly needs further study. I think both neopterin and beta 2 microglobulin should be considered as potential markers for HIV progression, or for measuring a response to therapy, particularly for neurologists treating HIV.

DS: What would you say is useful for clinicians to look for in terms of nutritional deficiencies in HIV infection?

NG: I think I'd definitely look for B12 and folate. They both tend to drop relatively early on in HIV, they are deficiencies that are known to cause problems, and they are potentially reversible. Zinc could be useful as a marker for progression. Body mass and weight loss should definitely be monitored. From our studies in the Multicenter AIDS Cohort Study we have noted a mild weight loss well before the progression to AIDS, and if you're going to intervene nutritionally, maybe it's worth starting before the appearance of major symptoms.

DS: What are your thoughts on the value of beta carotene in immune function?

NG: Beta Carotene and vitamin A are of a lot of interest generally in developing countries, for benefiting eye problems as well as acute respiratory infections and diarrheal infections. They play an important role in immune function, especially in regard to surfaces lined with epithelial cells, which of course include the sites of respiratory and diarrheal infections. Vitamin A pretty clearly reduces morbidity and perhaps even mortality in children who suffer from deficiencies.

DS: Is there a caution against people taking too much vitamin A, especially people who are having drug-induced liver problems, or histories of hepatitis?

NG: Oh yes, that could be very dangerous. Nutrition as a discipline has gotten a bad name, because to some people it means doing what their mother told them to do, or what the local health food store is promoting.

DS: Unfortunately, it's true. At least one vitamin store in San Francisco sells nutritional "consultations," during which some people have been told that they cannot be healthy as long as they take AZT.

NG: That's very dangerous, and it happens a lot, not just to people with HIV, but everyone with chronic diseases - cancer, asthma, etc. Nutrition is very hard to study scientifically, but we should be doing it. As more and more opportunistic infections come under control, nutritional changes and weight loss will become increasingly apparent, and we'll have to deal with it in a reasonable manner. ▼

Proposed AIDS Definition Change

(By Laura Thomas)

{reprinted with permission from AIDS Treatment News #132, 8/9/91}

The Centers for Disease Control (CDC) is proposing to revise the surveillance definition of AIDS in adults and adolescents to include anyone who is HIV positive and has 200 or fewer T-helper cells (also known as CD4 cells). This will increase the number of people with HIV who are eligible for free health care and other benefits. The change comes in response to great pressure on the CDC from all sides, ranging from ACT UP to the American Medical Association. However, the activists who organized the campaign to change the definition of AIDS feel that this revision does not address their primary concerns, and that more pressure is still needed to make the definition reflect the reality of the epidemic. The CDC has said that barring any unforeseen circumstances, the new definition would go into effect January 1, 1992. The definition was last revised in 1987.

The proposed definition will have a huge impact on the face of AIDS in the U.S. Obviously, changing the definition is not going to make anyone sicker or healthier, but it will greatly increase the numbers of people with an official AIDS diagnosis. On the positive side, more people will be able to qualify for disability, housing, medical care, and other benefits that can depend on an AIDS diagnosis, and more people may seek medical care.

We have heard several reactions from people who would be affected by the proposed revision. One woman with HIV wondered aloud just how sick she would have to get to have her T-cells hit 200 so that she could receive the benefits that depend on an AIDS diagnosis. On the other hand, for some people the emotional impact of waking up on January 1 with a diagnosis they had successfully avoided for years will be rough.

Activists who have been pushing the CDC for over two years to revise the AIDS definition are disappointed by the proposed change. The definition as it stands now does not include any of the AIDS-related opportunistic infections that are specific to women, such as vaginal candidiasis, cervical cancer, and chronic pelvic inflammatory disease, nor a host of other disabling HIV-related conditions that are common in injection drug users (IDUs) and people of color, including women. Because the definition of AIDS has reflected the historical experience in gay men, many women have died of AIDS without ever having an official diagnosis, sometimes without being eligible for the benefits they need. The proposed change would help some of these people, but it does not address other issues raised by activists, nor would it require the CDC to acknowledge that AIDS is different for women or to keep statistics on the opportunistic infections that are specific to women and IDUs.

Another problem is the uncertainty of T-cell tests. They are not designed as screening tests, and so are not as carefully calibrated as the HIV antibody test, for example, T-cell counts on the same person can vary from lab to lab, not to mention from hour to hour. While it does give a general indication of the status of one's immune system, it may be problematic as an AIDS-defining indicator. We also know very little about how T-cell counts are related to progression of disease in women. Judith Cohen of Project AWARE in San Francisco said that there is a suspicion that T-cell counts vary more widely in women, possibly due to menstrual cycle fluctuations, but that no one knows what "normal" T-cells are like in women. Many women will qualify under this definition, but it could turn out that women will still be dying without an official diagnosis.

Dr. George Lemp in the San Francisco AIDS Office estimated that the numbers of living people with AIDS in San Francisco could more than double under this revision. Some areas of the country will see an even greater increase. Federal funding that is dependent on AIDS case loads, such as the Ryan White/CARE bill, will have to be reallocated, and unless federal funds are boosted, dollars will have to be spread over a larger area, resulting in service cuts that could leave cities unable to keep us with the increased demand. The change will certainly help many people, but it will do little to address the underlying problems that led to the call for a revised definition. ▼

Foscarnet Approved

{reprinted from AIDS Treatment News, Issue 136, 10/11/91}

On September 27, the U.S. Food and Drug Administration (FDA) approved foscarnet (brand name Foscavir) for treatment of CMV retinitis. In the U.S., foscarnet has been available since August 1990 for treating CMV retinitis which does not respond to ganciclovir. In Europe, the drug has been routinely used for years, often as a first-line treatment for CMV.

FDA Commissioner David Kessler, M.D., said that "the availability of an alternative treatment for this disease adds a new dimension in the fight against AIDS, as it gives patients and physicians more options in combating this disease. FDA is determined to help broaden the array of drugs to treat AIDS and related conditions."

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Lymphoma: New Agent Under Study

{By Denny Smith; reprinted with permission AIDS Treatment News, Issue #136, 10/11/91}

Anti-B4 blocked ricin, or Oncolysin B, is a new drug now entering phase I and II trials to treat HIV-associated lymphoma. Lymphoma is usually treated with conventional chemotherapy drugs and radiation; experimental approaches have produced mostly disappointing results.

Oncolysin B was developed by ImmunoGen, Inc., of Cambridge, Massachusetts, which already has the drug under investigation for the treatment of certain leukemias and non-AIDS-related lymphoma. In those trials, Oncolysin B has been found not to decrease white cell counts, which is one of the serious drawbacks of more established therapies.

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{Foscarnet Approved; cont'd}

The approval does not include the other important uses for foscarnet - treatment of CMV in organs other than the retina, and treatment of acyclovir-resistant herpes. Physicians will be free to prescribe the drug for these purposes, but insurance companies are likely to use the FDA "labeling" as an excuse not to pay. And the drug will be expensive; we have heard the figure of $58 per day wholesale. The company, Astra Pharmaceutical Products, is setting up a program to help persons unable to pay for the drug.

Foscarnet has considerable toxicity, and a number of precautions are necessary for using it safely. ▼

{Lymphoma: New Agent Under Study; cont'd}

ImmunoGen told us that the current trials are expected to fill quickly, but that the drug is also expected to pass safety questions quickly. When that happens, larger efficacy trials will open to recruitment. Meanwhile, an additional protocol designed to combine Oncolysin B with a standard chemotherapy regimen is planned for the near future. For any of these trials, the number for interested physicians to call is 800/446-9633 or 617/661-9312, between 8:00 a.m. and 6:00 p.m. Eastern time. ▼

Newly Recognized, Treatable Organism May Mimic KS - or Other AIDS Diagnoses

{by Denny Smith; reprinted with permission from AIDS Treatment News #129, 7/26/91}

A newly described micro-organism has been found to cause opportunistic infections in persons with HIV - infections which can mimic symptoms of Kaposi's sarcoma (KS) and Mycobacterium avium complex (MAC, also called MAI). The infectious agent is a previously unknown bacillus which is believed to be related to Rochalimaea quintana. The bacillus was thoroughly discussed last December 6 in a group of reports in *The New England Journal of Medicine.*

Infection with this organism can lead to bacillary angiomatosis, hepatic peliosis, bacteremia, and possibly cat-scratch disease. Last month, Colin Blakeney, a friend of *AIDS Treatment News* and a member of ACT UP/San Francisco, called us to share first hand experience with this infection. We want in turn to share with readers what he learned, as well as some observations of a national expert on the new bacillus, Philip E. LeBoit, M.D., a pathologist at the University of California San Francisco School of Medicine.

Since January of this year, Colin had been experiencing symptoms suggestive of infections of Mycobacterium avium complex (MAC, or MAI): intermittent chills, very high fevers, anemia and loss of appetite. Several months earlier he had been diagnosed with Kaposi's sarcoma, based on a biopsy of a single lesion.

After more than 100 various tests failed to explain Colin's constitutional symptoms, doctors removed one of his lymph nodes. An analysis of the node revealed the same infection described above. He was started on 1500 mg daily doses of the antibiotic ciprofloxacin, and the symptoms responded within several days. Unfortunately, the ciprofloxacin seemed to stop working after two weeks, and he was switched to doxycycline, which has apparently worked for the last four weeks.

His doctors are now suspicious of the lab report that identified the KS lesion. Because of the nature of angiomatosis, they are re-evaluating the biopsy to rule out the possibility that the lesion was misidentified as KS. Colin feels that it is now very important for everyone with HIV, and their primary physicians, to be aware of the possibility of this bacillus posing as other opportunistic infections or as KS.

Although the particular species of this bacillus has not been named or categorized yet, its discovery might have some very important consequences. For example, how many people who have been diagnosed and treated for symptoms of KS, or MAC, actually are dealling with this bacillus? Could this explain why some people do not respond to the current KS and MAC therapies? Could this explain why the empirical use of antibiotics like doxycycline seems to help symptoms which have eluded diagnosis? What is the potential for this bacillus to operate as a cofactor in the progression of HIV, as mycoplasma and herpes infections have been alleged to do? We are eager for answers to such questions, answers which might go a long way toward solving the puzzle of HIV disease.

Dr. LeBoit has been working toward those answers. He told us that this bacillus has no doubt existed since before the AIDS epidemic, but probably does not cause disease in persons without immune deficiency. Unfortunately, nearly all of the symptoms associated with the bacillus - fevers, profound anemia, lymphadenopathy, splenomegaly and skin lesions - can easily be attributed to other opportunistic conditions.

In view of the skin lesions and the prevalence of KS in the epidemic, Dr. LeBoit estimates that potentially one of every fifty KS diagnoses is actually angiomas caused by this bacillus. This could explain why some people's lesions never respond to chemotherapeutic agents, as well as why some "MAC-type" symptoms persist during MAC treatment.

However, the bacillus does respond effectively to some antibiotics; Dr. LeBoit's first choice is erythromycin, 2 grams daily. He feels that doxycycline is an effective choice as well, only more expensive. Treatment in this case is simpler than diagnosis, which must be done by a knowledgeable pathologist. Pathologists and clinicians alike who are interested in the criteria for identifying this infection, which may include a liver biopsy, can obtain them in an early article describing the bacillus - volume 13 of the *American Jouranl of Surgical Pathology*, 1989, pages 909 to 920. Dr. LeBoit emphasized that non-dermatologists working without a biopsy cannot definitively diagnose the infection. ▼

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ALERT is a monthly newsletter containing information on AIDS Legislation, Education, Research and Treatment. The Editor is Rev. Dr. Stephen Pieters. For information, please write to: ALERT, c/o UFMCC, 5300 Santa Monica Blvd., Suite 304, Los Angeles, CA 90029.